

able for administration in medical use. It should be appreciated that the determinations of proper dosage forms, dosage amounts, and routes of administration for a particular patient are within the level of ordinary skill in the pharmaceutical and medical arts.

Administration is typically oral but other routes of administration are useful, e.g., parenteral, nasal, buccal, transdermal, sublingual, intramuscular, intravenous, rectal, vaginal, etc. Solid dosage forms for oral administration include capsules, tablets, pills, powders, and granules. In such solid dosage forms, the compound is admixed with at least one inert pharmaceutically acceptable excipient such as (a) fillers or extenders, as for example, starches, lactose, sucrose, glucose, mannitol, and silicic acid, (b) binders, as for example, carboxymethylcellulose, alginates, gelatin, polyvinylpyrrolidone, sucrose, and acacia, (c) humectants, as for example, glycerol, (d) disintegrating agents, as for example, agar-agar, calcium carbonate, potato or tapioca starch, alginic acid, certain complex silicates, and sodium carbonate, (e) solution retarders, as for example paraffin, (f) absorption accelerators, as for example, quaternary ammonium compounds, (g) wetting agents, as for example, cetyl alcohol, and glycerol monostearate, (h) adsorbents, as for example, kaolin and bentonite, and (i) lubricants, as for example, talc, calcium stearate, magnesium stearate, solid polyethylene glycols, sodium lauryl sulfate, or mixtures thereof. In the case of capsules, tablets, and pills, the dosage forms may also comprise buffering agents. Solid dosage forms such as tablets, dragees, capsules, pills, and granules also can be prepared with coatings and shells, such as enteric coatings and others well known in the art. The solid dosage form also may contain opacifying agents, and can also be of such composition that they release the active compound or compounds in a certain part of the intestinal tract in a delayed manner. Examples of embedding compositions which can be used are polymeric substances and waxes. The active compounds can also be in micro-encapsulated form, if appropriate, with one or more of the above-mentioned excipients. Such solid dosage forms may generally contain from 1% to 95% (w/w) of the active compound. In certain embodiments, the active compound ranges from 5% to 70% (w/w).

Solid compositions for oral administration can be formulated in a unit dosage form, each dosage containing from about 1 to about 100 mg of active ingredient. The term "unit dosage form" refers to physically discrete units suitable as unitary dosages for human subjects and other mammals, each unit containing a predetermined quantity of active material calculated to produce the desired prophylactic or therapeutic effect over the course of a treatment period, in association with the required pharmaceutical carrier. Tasimelteon can be formulated, e.g., in a unit dosage form that is a capsule having 20 mg of active in addition to excipients.

Liquid dosage forms for oral administration include pharmaceutically acceptable emulsions, solutions, suspensions, syrups, and elixirs. In addition to the compound or composition, the liquid dosage forms may contain inert diluents commonly used in the art, such as water or other solvents, solubilizing agents and emulsifiers, as for example, ethyl alcohol, isopropyl alcohol, ethyl carbonate, ethyl acetate, benzyl alcohol, benzyl benzoate, propyleneglycol, 1,3-bu-

tyleneglycol, dimethylformamide, oils, in particular, cottonseed oil, groundnut oil, corn germ oil, olive oil, castor oil and sesame oil, glycerol, tetrahydrofurfuryl alcohol, polyethyleneglycols and fatty acid esters of sorbitan or mixtures of these substances. Besides such inert diluents, the composition can also include adjuvants, such as wetting agents, emulsifying and suspending agents, sweetening, flavoring, and perfuming agents.

The present invention can be carried out in conjunction with other treatment approaches, e.g., in combination with a second or multiple other active pharmaceutical agents, including but not limited to other agents that affect insomnia, sleep-wake patterns, vigilance, depression, or psychotic episodes.

While this invention has been described in conjunction with the specific embodiments outlined above, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art or are otherwise intended to be embraced. Accordingly, the embodiments of the invention as set forth above are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention as defined in the following claims. All patents, patent application, scientific articles and other published documents cited herein are hereby incorporated in their entirety for the substance of their disclosures.

What is claimed is:

1. A method of treating a disorder associated with a desynchronous cortisol circadian rhythm in an individual having a desynchronous cortisol circadian rhythm, said method comprising internally administering to the individual an effective amount of tasimelteon,

wherein the disorder associated with a desynchronous cortisol circadian rhythm is selected from a group consisting of: obesity, depression, and neurological impairment.

2. The method of claim 1, wherein the individual is light perception impaired (LPI).

3. The method of claim 1, wherein the individual is totally blind.

4. The method of claim 1, wherein the individual suffers from Non-24-Hour Sleep-Wake Disorder.

5. The method of claim 1, wherein the effective amount is an amount sufficient to entrain the individual's cortisol circadian rhythm to a natural day/night cycle comprising a 24-hour sleep-wake cycle in which the individual awakens at or near a target wake time following a daily sleep period of approximately seven to nine hours.

6. The method of claim 1, wherein the tasimelteon or active metabolite thereof is administered 0.5 hour to 1.5 hours before a target bedtime.

7. The method of claim 1, wherein the administering includes administering between about 10 mg and about 100 mg of tasimelteon.

8. The method of claim 1, wherein the administering includes administering between about 20 mg and about 50 mg of tasimelteon.

9. The method of claim 1, wherein the administering includes administering about 20 mg of tasimelteon.

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